

EXHIBIT A

CONFIDENTIAL – FILED UNDER SEAL

EXHIBIT B

CONFIDENTIAL – FILED UNDER SEAL

EXHIBIT C



[FDA Home Page](#) | [CDER Home Page](#) | [CDER Site Info](#) | [Contact CDER](#) | [What's New @ CDER](#)


[CDER Home](#) [About CDER](#) [Drug Information](#) [Regulatory Guidance](#) [CDER Calendar](#) [Specific Audiences](#) [CDER Archives](#)

Search powered by Google™

Paragraph IV Patent Certifications As of June 22, 2006

Below is a list of drug products for which an Abbreviated New Drug Application (ANDA) has been received by the Office of Generic Drugs (OGD) containing a "Paragraph IV" patent certification. This list includes the name of the drug product, dosage form, strength (subject of Paragraph IV certification), reference listed drug (RLD), and the date on which the first substantially complete generic drug application was submitted to the Agency (on a prospective basis beginning 3/2/04). The Agency will not disclose the identity of the applicant. This information will be updated on a bi-monthly basis and will be as current as the last update. This information should be used for reference only. The Agency will make every effort to ensure the accuracy of the information disclosed in this list. However, any discrepancies or disparities should be discussed with the Regulatory Support Branch at 301-827-5862, before making any decisions based on this information.

Any additions from the preceding list are marked with the **New!!** icon.

- [FDA News: FDA announces measure to improve generic drug access](#)
- [Docket # 2000P-1556 Policy regarding ANDA holder confidentiality](#) 

DRUG NAME	DOSAGE FORM	STRENGTH	RLD	DATE OF SUBMISSION
Acarbose	Tablets	25 mg, 50 mg and 100 mg	Precose	3/22/2005
Acetaminophen	Extended-release Tablets	650 mg	Tylenol	
Acetaminophen/ Aspirin/ Caffeine	Tablets	250 mg/250 mg/ 65 mg	Excedrin (migraine)	
Acetaminophen and Tramadol Hydrochloride	Tablets	325 mg/ 37.5 mg	Ultracet	
Acyclovir Sodium	Injection	50 mg/mL, 10 mL and 20 mL vials	Zovirax	

Adenosine	Injection	3 mg/mL, 20 mL and 30 mL vials	Adenoscan	4/18/2005
Albuterol Sulfate	Oral Syrup	2 mg(base)/ 5 mL	Ventolin	
Albuterol Sulfate	Extended-release Tablets	4 mg and 8 mg	Volmax	
Albuterol Sulfate	Inhalation Solution	0.021% and 0.042%	Accuneb	10/19/2005
Albuterol Sulfate/ Ipratropium Bromide	Inhalation Solution	0.083%/ 0.017%	Duoneb	
Alendronate Sodium	Tablets	5 mg, 10 mg, 35 mg, 40 mg and 70 mg	Fosamax	
Alprazolam	Orally Disintegrating Tablets	0.25 mg, 0.5 mg, 1 mg and 2 mg	Niravam	12/27/2005
Alprazolam	Tablets	0.25 mg, 0.5 mg, 1 mg and 2 mg	Xanax	
Almotriptan Malate	Tablets	6.25 mg and 12.5 mg	Axert	12/8/2005
Amifostine	For Injection	500 mg/vial	Ethyol	4/16/2004
Amlodipine Besylate	Tablets	2.5 mg, 5 mg and 10 mg	Norvasc	
Amlodipine Besylate and Benazepril Hydrochloride	Capsules	2.5 mg/10 mg, 5 mg/10 mg, 5 mg/20 mg and 10 mg/20 mg	Lotrel	6/9/2004
Atenolol	Tablets	25 mg, 50 mg and 100 mg	Tenormin	
Atenolol/ Chlorthalidone	Tablets	50 mg/25 mg and 100 mg/25 mg	Tenoretic	
Atorvastatin Calcium	Tablets	10 mg, 20 mg, 40 mg and 80 mg	Lipitor	
Azelastine Hydrochloride	Nasal Spray	0.125 mg base/spray	Astelin	11/14/2005
Betaxolol	Ophthalmic	0.5%(base)	Betoptic	

	Solution			
Brimonidine Tartrate	Ophthalmic Solution	0.2%	Alphagan	
Budesonide	Inhalation Suspension	0.25 mg/2 mL and 0.5 mg/2 mL	Pulmicort Respules	9/15/2005
Bupropion Hydrochloride	Extended-release Tablets	100 mg, 150 mg and 200 mg	Wellbutrin SR	
Bupropion Hydrochloride	Extended-release Tablets	150 mg	Zyban	
Bupropion Hydrochloride	Extended-release Tablets	150 mg and 300 mg	Wellbutrin XL	9/21/2004
Bupropion Hydrochloride	Tablets	75 mg and 100 mg	Wellbutrin	
Buspirone Hydrochloride	Tablets	5 mg, 7.5 mg, 10 mg, 15 mg and 30 mg	Buspar	
Butorphanol Tartrate	Nasal Spray	10 mg/mL	Stadol NS	
Calcitonin-Salmon	Nasal Spray	200 IU/spray	Miacalcin	
Calcitriol	Injection	1 mcg/mL and 2 mcg/mL, 1 mL vials	Calcijex	
Calcium Acetate	Capsules	EQ 169 mg calcium	PhosLo	5/31/2005
Calcium Carbonate/ Famotadine/ Magnesium Hydroxide	Chewable Tablets	800 mg/ 10 mg/ 165 mg (OTC)	Pepcid Complete	11/1/2004
Captopril	Tablets	12.5 mg, 25 mg, 50 mg, and 100 mg	Capoten	
Carbamazepine	Extended-release Capsules	100 mg and 200 mg	Carbatrol	2/2/2006
Carbamazepine	Extended-release Capsules	300 mg	Carbatrol	
Carbamazepine	Extended-release Tablets	100 mg	Tegretol-XR	12/30/2005
Carbamazepine	Extended-release Tablets	200 mg and 400 mg	Tegretol-XR	

Carbidopa/ Levodopa	Extended-release Tablets	25 mg/100 mg and 50 mg/200 mg	Sinemet CR	
Carboplatin	For Injection	50 mg/vial, 150 mg/vial and 450 mg/vial	Paraplatin	
Carboplatin	Injection	50 mg/vial, 150 mg/vial and 450 mg/vial	Paraplatin	
Carisoprodol/ Aspirin	Tablets	200 mg/ 325 mg	Soma Compound	
Carisoprodol/ Aspirin/ Codeine	Tablets	200 mg/ 325 mg/ 16 mg	Soma Compound with Codeine	
Carvedilol	Tablets	3.125 mg, 6.25 mg, 12.5 mg and 25 mg	Coreg	
Celecoxib	Capsules	100 mg, 200 mg and 400 mg	Celebrex	
Cetirizine Hydrochloride and Pseudoephedrine	Extended-release Tablets	5 mg/120 mg	Zyrtec-D	6/2/2004
Cetirizine Hydrochloride	Chewable Tablets	5 mg and 10 mg	Zyrtec	3/25/2005
Chlorhexidine Gluconate	Scrub brush/sponge	4%	Hibiclens	
Chlorpheniramine Polistirex and Hydrocodone Polistirex	Extended-release Capsules	8 mg/10 mg and 4 mg/5 mg	Tussionex	9/10/2004
Ciprofloxacin Hydrochloride	Tablets	100 mg, 250 mg, 500 mg and 750 mg	Cipro	
Cisplatin	Injection	1 mg/mL, 10 mL, 50 mL, 100 mL and 200 mL vials	Platinol-AQ	
Cisplatin	For Injection	10 mg/vial and 50 mg/vial	Platinol	
Clobetasol Propionate	Topical Foam	0.05%	Olux	6/27/2005

Clobetasol Propionate	Lotion	0.05%	Clobex	3/27/2006
Clonidine Hydrochloride	Transdermal System	0.1 mg/day, 0.2 mg/day, and 0.3 mg/day	Catapres-TTS	
Clopidogrel Bisulfate	Tablets	75 mg	Plavix	
Colestipol Hydrochloride	Tablets	1 g	Colestid	8/23/2005
Conjugated Estrogens	Tablets	0.3 mg and 0.625 mg	Premarin	
Cyclobenzaprine Hydrochloride	Tablets	10 mg	Flexeril	
Cyclophosphamide	For Injection	100 mg/vial, 200 mg/vial, 500 mg/vial, 1 g/vial and 2 g/vial	Cytosan	
Desmopressin Acetate	Injection	4 mcg/mL, 1 mL and 10 mL vials	DDAVP	
Desmopressin Acetate	Nasal Spray	0.01%	DDAVP	
Desmopressin Acetate	Tablets	0.1 mg and 0.2 mg	DDAVP	
Desogestrel; Ethinyl Estradiol Tablets	Tablets	0.15mg/ 0.02 mg and 0.01 mg	Mircette	
Dexmethylphenidate Hydrochloride	Tablets	2.5 mg	Focalin	7/27/2004
Dexmethylphenidate Hydrochloride	Tablets	5 mg and 10 mg	Focalin	5/27/2004
Dexrazoxane	For Injection	250 mg/vial	Zinecard	
Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate	Extended-release Capsules	5 mg, 10 mg, 15 mg, 20 mg, 25 mg and 30 mg	Adderall XR	
Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate	Tablets	7.5 mg, 12.5 mg and 15 mg	Adderall	
Diazepam	Tablets	2 mg, 5 mg and 10 mg	Valium	
Diazepam	Rectal Gel	2.5 mg/0.5 mL, 5 mg/mL, 10	Diastat	3/23/2004

		mg/2 mL, 15 mg/3 mL and 20 mg/4 mL		
Didanosine	Delayed-release Capsules	200 mg, 250 mg and 400 mg	Videx EC	6/1/2004
Diltiazem Hydrochloride	Extended-release Capsules	60 mg, 90 mg and 120 mg	Cardizem SR	
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg and 240 mg	Dilacor XR	
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg, 240 mg and 300 mg	Cardizem CD	
Diltiazem Hydrochloride	Extended-release Capsules	120 mg, 180 mg, 240 mg, 300 mg, 360 mg and 420 mg	Tiazac	
Diltiazem Hydrochloride	Extended-release Tablets	120 mg, 180 mg, 240 mg, 300 mg and 360 mg	Cardizem LA	8/30/2005
Diltiazem Hydrochloride	Extended-release Tablets	420 mg	Cardizem LA	4/25/2005
Divalproex Sodium	Delayed-release Tablets	125 mg, 250 mg and 500 mg	Depakote	
Divalproex Sodium	Extended-release Tablets	250 mg	Depakote ER	5/3/2004
Divalproex Sodium	Extended-release Tablets	500 mg	Depakote ER	2/8/2005
Donepezil Hydrochloride	Tablets	5 mg and 10 mg	Aricept	
Dorzolamide Hydrochloride	Ophthalmic Solution	2%	Trusopt	10/7/2005
Dorzolamide Hydrochloride and Timolol Maleate	Ophthalmic Solution	2%/0.5%	Cosopt	10/7/2005
Doxazosin Mesylate	Tablets	1 mg, 2 mg, 4 mg and 8 mg	Cardura	

Drospirenone and Ethinyl Estradiol	Tablets	3.0 mg/0.03 mg	Yasmin	1/7/2005
Enalapril Maleate	Tablets	2.5 mg, 5 mg, 10 mg and 20 mg	Vasotec	
Enoxaparin Sodium	Injection	100 mg/mL, 0.3 mL, 0.4 mL, 0.6 mL, 0.8 mL and 1 mL prefilled syringes	Lovenox	
Enoxaparin Sodium	Injection	150 mg/mL, 0.6 mL, 0.8 mL and 1 mL prefilled syringes	Lovenox	
Escitalopram Oxalate	Capsules	5 mg	Lexapro	8/17/2005
Escitalopram Oxalate	Capsules	10 mg and 20 mg	Lexapro	3/30/2005
Escitalopram Oxalate	Tablets	5 mg, 10 mg and 20 mg	Lexapro	
Esmolol Hydrochloride	Injection	10 mg/mL, 10 mL vial	Brevibloc	
Esomeprazole Magnesium	Delayed-release Capsules	20 mg and 40 mg	Nexium	8/5/2005
Estradiol	Transdermal System	0.0375 mg/day and 0.06 mg/day	Climara	
Estradiol	Transdermal System	0.05 mg/day and 0.1 mg/day	Climara	9/12/2005
Estradiol; Estradiol and Norgestimate	Tablets	1 mg; 1 mg and 0.09 mg	Prefest	
Etodolac	Extended-release Tablets	400 mg, 500 mg and 600 mg	Lodine XL	
Famciclovir	Tablets	125 mg, 250 mg and 500 mg	Famvir	12/28/2004
Famotidine	Injection	10 mg/mL, 2 mL vials; unpreserved	Pepcid	

Famotidine	Injection	10 mg/mL, 4 mL and 20 mL vials; preserved	Pepcid	
Famotidine	Injection	10 mg/mL, 50 mL vial, pharmacy bulk package; unpreserved	Pepcid	
Famotidine	Tablets	10 mg (OTC)	Pepcid AC	
Famotidine	Tablets	20 mg and 40 mg	Pepcid	
Famotidine	Tablets (Chewable)	10 mg (OTC)	Pepcid AC (chewable)	
Felodipine	Extended-release Tablets	2.5 mg, 5 mg and 10 mg	Plendil ER	
Fenofibrate	Capsules	67 mg, 134 mg and 200 mg	Tricor	
Fenofibrate	Tablets	54 mg, 107 mg and 160 mg	Tricor	
Fentanyl	Transdermal Extended-release Film	0.6 mg/24 hr, 1.2 mg/ 24 hr, 1.8 mg/ 24 hr and 2.4 mg/ 24 hr	Duragesic	
Fentanyl Citrate	Lozenges	0.2 mg	Actiq	10/29/2004
Fentanyl Citrate	Lozenges	0.4 mg	Actiq	10/6/2004
Fentanyl Citrate	Lozenges	0.6 mg	Actiq	12/20/2004
Fentanyl Citrate	Lozenges	0.8 mg, 1.2 mg and 1.6 mg	Actiq	11/22/2004
Fexofenadine Hydrochloride	Capsules	60 mg	Allegra	
Fexofenadine Hydrochloride	Tablets	30 mg, 60 mg and 180 mg	Allegra	
Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride	Extended-release Tablets	60 mg/120 mg	Allegra-D	
Finasteride	Tablets	1 mg	Propecia	
Finasteride	Tablets	5 mg	Proscar	
Flecainide Acetate	Tablets	50 mg, 100 mg and 150 mg	Tambocor	

Fluconazole	For Oral Suspension	50 mg/5 mL and 200 mg/5 mL	Diflucan for Oral Suspension	
Fluconazole	Tablets	50 mg, 100 mg, 150 mg and 200 mg	Diflucan	
Flunisolide	Nasal Solution	0.025%	Nasalide	
Fluocinonide	Ointment	0.05%	Lidex	
Fluoxetine Hydrochloride	Tablets	10 mg and 20 mg	Prozac	
Fluoxetine Hydrochloride	Capsules	10 mg, 20 mg and 40 mg	Prozac	
Fluoxetine Hydrochloride	Delayed-release Capsules	90 mg	Prozac Weekly	
Fluoxetine Hydrochloride	Oral Solution	20 mg (base)/5 mL	Prozac	
Fluoxetine Hydrochloride	Capsules	10 mg and 20 mg	Sarafem	
Flutamide	Capsules	125 mg	Eulexin	
Fosinopril Sodium	Tablets	10 mg, 20 mg and 40 mg	Monopril	
Fosinopril Sodium and Hydrochlorothiazide	Tablets	10 mg/12.5 mg and 20 mg/12.5 mg	Monopril HCT	
Gabapentin	Capsules	100 mg, 300 mg and 400 mg	Neurontin	
Gabapentin	Oral Solution	250 mg/5 mL	Neurontin	
Gabapentin	Tablets	100 mg, 300 mg and 400 mg	Neurontin	
Gabapentin	Tablets	600 mg and 800 mg	Neurontin	
Galantamine Hydrobromide	Extended-release Capsules	8 mg	Razadyne ER	3/2/2006
Galantamine Hydrobromide	Extended-release Capsules	16 mg and 24 mg	Razadyne ER	3/11/2006
Galantamine Hydrobromide	Tablets	4 mg, 8 mg	Razadyne	2/28/2005

		and 12 mg		
Ganciclovir Sodium	Capsules	250 mg and 500 mg	Cytovene	
Gatifloxacin	Injection	10 mg/mL, 20 mL and 40 mL vials	Tequin	11/24/2004
Gatifloxacin	Tablets	200 mg and 400 mg	Tequin	
Gatifloxacin in Dextrose 5% in Plastic Container	Injection	2 mg/mL, 100 mL and 200 mL containers (plastic)	Tequin	12/13/2004
Gemcitabine	For Injection	200 mg/vial	Gemzar	11/1/2005
Gemcitabine	For Injection	1g/vial	Gemzar	11/14/2005
Glipizide	Extended-release Tablets	2.5 mg, 5 mg and 10 mg	Glucotrol XL	
Glyburide	Tablets	1.5 mg, 3 mg, 4.5 mg and 6 mg	Glynase	
Glyburide/ Metformin Hydrochloride	Tablets	1.25mg/250 mg, 2.5 mg/500 mg and 5 mg/500 mg	Glucovance	
Granisetron Hydrochloride	Injection	1 mg/mL, 1 mL vials	Kytril	6/1/2004
Granisetron Hydrochloride	Injection	1 mg/mL, 4 mL multi-dose vials	Kytril	7/19/2004
Hydrocodone Bitartrate and Ibuprofen	Tablets	2.5 mg/200 mg	Vicoprofen	2/24/2006
Hydrocodone Bitartrate and Ibuprofen	Tablets	5 mg/200 mg	Vicoprofen	5/27/2005
Hydrocodone Bitartrate and Ibuprofen	Tablets	7.5 mg/200 mg	Vicoprofen	
Hydrocodone Bitartrate and Ibuprofen	Tablets	10 mg/200 mg	Vicoprofen	
Ibuprofen	Oral Drops	40 mg/mL	Children's Motrin Drops	
Ibuprofen	Oral Suspension	100 mg/5 mL (Rx)	Motrin	

Ibuprofen	Oral Suspension	100 mg/5 mL (OTC)	Children's Motrin	
Ibuprofen	Chewable Tablets	50 mg and 100 mg	Children's Motrin, Junior Strength Motrin	
Ibuprofen Potassium and Pseudoephedrine Hydrochloride	Capsules	200 mg/30 mg	Advil Cold and Sinus	12/27/2004
Ibuprofen and Pseudoephedrine Hydrochloride	Oral Suspension	100 mg/ 15 mg per 5 mL	Children's Motrin Cold	
Ibuprofen and Pseudoephedrine Hydrochloride	Tablets	200 mg/30 mg	Advil Cold and Sinus	
Ifosfamide	For Injection	1 g/vial and 3 g/vial	Ifex	
Ifosfamide	Injection	50 mg/mL, 20 mL vials and 60 mL vials	Ifex	
Ifosfamide/ Mesna	For Injection/ Injection Kit	1 g/vial; 100 mg/mL, 10 mL vials and 3 g/vial; 100 mg/mL, 10 mL vials	Ifex/ Mesnex Kit	
Ifosfamide/ Mesna	Injection/ Injection Kit	50 mg/mL, 20 mL and 60 mL vials; 100 mg/mL, 10 mL vial	Ifex/ Mesnex Kit	
Indomethacin	Extended-release Capsules	75 mg	Indocin SR	
Irbesartan	Tablets	75 mg, 150 mg and 300 mg	Avapro	5/25/2004
Irbesartan and Hydrochlorothiazide	Tablets	150 mg/12.5 mg and 300 mg/12.5 mg	Avalide	11/10/2004
Irinotecan Hydrochloride	Injection	20 mg/mL, 2 mL and 5 mL vials	Camptosar	7/26/2004
Itraconazole	Capsules	100 mg	Sporanox	
Ketoprofen	Capsules	25 mg, 50 mg and 75 mg	Orudis	

Ketorolac Tromethamine	Injection	15 mg/mL and 30 mg/mL	Toradol	
Ketorolac Tromethamine	Ophthalmic Solution	0.5%	Acular	
Ketorolac Tromethamine	Ophthalmic Solution	0.4%	Acular LS	1/28/2005
Ketorolac Tromethamine	Tablets	10 mg	Toradol	
Ketotifen Fumarate	Ophthalmic Solution	0.025%	Zaditor	12/23/2004
Lactulose	Oral Syrup	10 g/15 mL	Cephulac	
Lactulose	Oral Syrup	10 g/15 mL	Chronulac	
Lamotrigine	Tablets	25 mg, 100 mg, 150 mg and 200 mg	Lamictal	
Lamotrigine	Chewable Tablets	2 mg, 5 mg and 25 mg	Lamictal CD	
Latanoprost	Ophthalmic Solution	0.005%	Xalatan	
Lansoprazole	Delayed-release Pellets/Capsules	15 mg and 30 mg	Prevacid	12/05/2005
Letrozole	Tablets	2.5 mg	Femara	3/2/2006
Leuprolide Acetate	Injection (depot)	7.5 mg/vial	Lupron Depot	
Levalbuterol Hydrochloride	Inhalation Solution	0.0103%, 0.021% and 0.042%	Xopenex	6/20/2005
Levetiracetam	Tablets	250 mg, 500 mg and 750 mg	Keppra	
Levofloxacin	Injection	5 mg/mL; 50 mL, 100 mL and 150 mL vials	Levaquin in Dextrose 5% in Plastic Container	
Levofloxacin	Injection	25 mg/mL	Levaquin	
Levofloxacin	Ophthalmic Solution	0.5%	Quixin	
Levofloxacin	Tablets	250 mg, 500 mg and 750 mg	Levaquin	
Levonorgestrel and Ethinyl Estradiol	Tablets	0.15 mg/0.03 mg	Seasonale	3/29/2004

Levothyroxine Sodium	Tablets	0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.1 mg, 0.112 mg, 0.125 mg, 0.150 mg, 0.175 mg, 0.2 mg and 0.3 mg	Levoxyl	
Linezolid	Tablets	600 mg	Zyvox	12/21/2005
Loperamide HCl and Simethicone	Chewable Tablets	2 mg/125 mg	Imodium Advanced	
Loperamide HCl and Simethicone	Tablets	2 mg/125 mg	Imodium Advanced	12/29/2004
Loratadine	Syrup	1 mg/mL	Claritin	
Loratadine	Tablets	10 mg	Claritin	
Loratadine	Orally Disintegrating Tablets	10 mg	Claritin RediTabs	
Loratadine/ Pseudoephedrine	Extended-release Tablets	5 mg/120 mg	Claritin D-12 hour	
Loratadine/ Pseudoephedrine	Extended-release Tablets	10 mg/240 mg	Claritin D-24 hour	
Losartan Potassium	Tablets	25 mg, 50 mg, and 100 mg	Cozaar	
Losartan Potassium and Hydrochlorothiazide	Tablets	50 mg/12.5 mg and 100 mg/25 mg	Hyzaar	5/24/2004
Losartan Potassium and Hydrochlorothiazide	Tablets	100 mg/12.5 mg	Hyzaar	4/4/2006
Mefloquine Hydrochloride	Tablets	250 mg	Lariam	
Megestrol Acetate	Oral Suspension	40 mg/mL	Megace	
Metaxalone	Tablets	400 mg	Skelaxin	
Metaxalone	Tablets	800 mg	Skelaxin	11/4/2004
Metformin Hydrochloride	Extended-release Tablets	500 mg	Glucophage XR	
Metformin Hydrochloride	Extended-release Tablets	750 mg	Glucophage XR	
Methylphenidate Hydrochloride	Extended-release	10 mg, 20 mg and 30 mg	Metadate CD	5/13/2005

	Capsules			
Methylphenidate Hydrochloride	Extended-release Tablets	18 mg, 27 mg, 36 mg and 54 mg	Concerta	7/19/2005
Metoclopramide Hydrochloride	Injection	5 mg/mL, 2 mL, 10 mL, 20 mL and 30 mL vials	Reglan	
Metoprolol Succinate	Extended-release Tablets	25 mg, 50 mg, 100 mg and 200 mg	Toprol XL	
Metronidazole	Vaginal Gel	0.75%	MetroGel-Vaginal	9/2/2004
Mirtazapine	Tablets	7.5 mg, 15 mg, 30 mg, and 45 mg	Remeron	
Mirtazapine	Orally Disintegrating Tablets	15 mg, 30 mg and 45 mg	Remeron SolTab	
Modafinil	Tablets	100 mg and 200 mg	Provigil	
Moexipril Hydrochloride	Tablets	7.5 mg and 15 mg	Univasc	
Moexipril Hydrochloride and Hydrochlorothiazide	Tablets	7.5mg/12.5mg 15 mg/25 mg and 15 mg/12.5 mg	Uniretic	1/15/2004
Mometasone Furoate	Topical Solution (Cream)	0.1%	Elocon	
Mometasone Furoate	Topical Solution (Lotion)	0.1%	Elocon	6/10/2004
Moxifloxacin Hydrochloride	Ophthalmic Solution/Drops	0.5%	Vigamox	12/22/2005
Moxifloxacin Hydrochloride	Tablets	400 mg	Avelox	
Nabumetone	Tablets	500 mg and 750 mg	Relafen	
Naproxen Sodium	Extended-release Tablets	375 mg (base) and 500 mg (base)	Naprelan	
Nateglinide	Tablets	60 mg and 120 mg	Starlix	12/22/2004

Nefazodone HCl	Tablets	50 mg, 100 mg, 150 mg, 200 mg and 250 mg	Serzone	
Niacin	Extended-release Tablets	500 mg, 750 mg and 1000 mg	Niaspan	
Nicotine	Transdermal System	7 mg/day, 14 mg/day and 21 mg/day	Habitrol	
Nicotine Polacrilex	Troche/Lozenge	2 mg and 4 mg	Commit	
Nifedipine	Capsules	10 mg and 20 mg	Procardia	
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Adalat CC	
Nifedipine	Extended-release Tablets	30 mg, 60 mg and 90 mg	Procardia XL	
Nitrofurantoin Monohydrate/ Macrocrystals	Capsules	75 mg/25 mg	Macrobid	
Nitroglycerin	Sublingual Tablets	0.3 mg, 0.4 mg and 0.6 mg	Nitrostat	10/19/2005
Nitroglycerin	Transdermal System	0.1 mg/hr	Transderm-Nitro	
Nitroglycerin	Transdermal System	0.1 mg/hr, 0.2 mg/hr, 0.3 mg/hr, 0.4 mg/hr, 0.6 mg/hr and 0.8 mg/hr	Nitro-dur	
Nizatidine	Capsules	150 mg and 300 mg	Axid	
Norethindrone/ Ethinyl Estradiol	Tablets	0.5 mg/ 0.035 mg, 0.75 mg/ 0.035 mg and 1 mg /0.035 mg	Ortho-Novum 7/7/7, 21 and 28 day	
Norethindrone Acetate/ Ethinyl Estradiol	Tablets	1 mg/0.005 mg	Femhrt	
Norethindrone Acetate/ Ethinyl Estradiol	Tablets	1 mg/ 0.02 mg, 1 mg/0.03 mg and 1 mg /0.035 mg	Estrostep Fe	

Norethindrone Acetate/ Ethinyl Estradiol	Tablets	1 mg/0.02 mg, 1 mg/ 0.03 mg and 1 mg /0.035 mg	Estrostep 21	
Norethindrone Acetate/ Ethinyl Estradiol and Ferrous Fumarate New!!	Tablets New!!	1 mg/0.02 mg and 75 mg New!!	Loestrin 24 Fe New!!	4/17/2006 New!!
Norgestimate/ Ethinyl Estradiol	Tablets	0.18 mg /0.025 mg, 0.215 mg /0.025 mg and 0.25 mg /0.025 mg	Ortho Tri-Cyclen Lo, 28 day	
Norgestimate/ Ethinyl Estradiol	Tablets	0.18 mg /0.035 mg, 0.215 mg /0.035 mg and 0.25 mg /0.035 mg	Ortho Tri-Cyclen, 21 and 28 day	
Nortriptyline Hydrochloride	Capsules	10 mg, 25 mg, 50 mg and 75 mg	Pamelor	
Octreotide Acetate	Injection	0.05 mg /mL, 0.1 mg /mL and 0.5 mg/mL, 1 mL vials	Sandostatin (Preservative-free)	
Octreotide Acetate	Injection	0.2 mg/mL and 1 mg /mL, 5 mL vials	Sandostatin	
Ofloxacin	Otic Solution	0.3%	Floxin	
Olanzapine	Tablets	2.5 mg, 5 mg, 7.5 mg, 10 mg and 15 mg	Zyprexa	
Olanzapine	Tablets	20 mg	Zyprexa	
Olanzapine	Orally Disintegrating Tablets	5 mg, 10 mg, 15 mg and 20 mg	Zyprexa Zydis	
Olanzapine and Fluoxetine Hydrochloride	Capsules	6 mg/25 mg, 12 mg/25 mg, 6 mg/50 mg and 12 mg/50 mg	Symbyax	1/10/2005
Olmesartan Medoxomil New!!	Tablets New!!	5 mg, 20 mg and 40 mg	Benicar New!!	4/25/2006 New!!

		New!!		
Omeprazole	Delayed-release Capsules	10 mg, 20 mg and 40 mg	Prilosec	
Ondansetron Hydrochloride	Injection	2 mg/mL, 2 mL vials (Preservative-free)	Zofran	
Ondansetron Hydrochloride	Injection	2 mg/mL, 20 mL vials	Zofran	
Ondansetron Hydrochloride	Injection	0.64 mg/mL, 50 mL container (plastic)	Zofran in Plastic Container	
Ondansetron Hydrochloride	Oral Solution	4 mg/5 mL	Zofran	12/20/2004
Ondansetron Hydrochloride	Orally Disintegrating Tablets	4 mg and 8 mg	Zofran ODT	
Ondansetron Hydrochloride	Tablets	4 mg, 8 mg, 16 mg and 24 mg	Zofran	
Oxazepam	Capsules	10 mg, 15 mg and 30 mg	Serax	
Oxcarbazepine	Tablets	150 mg, 300 mg and 600 mg	Trileptal	5/3/2006
Oxybutynin Chloride	Extended-release Tablets	5 mg, 10 mg and 15 mg	Ditropan XL	
Oxycodone	Extended-release Tablets	10 mg, 20 mg, 40 mg, 80 mg and 160 mg	Oxycontin	
Paclitaxel	Injection	6 mg/mL, 5 mL, 16.7 mL, 25 mL, 33.3 mL and 50 mL vials	Taxol	
Pamidronate Disodium	For Injection	30 mg/vial, 60 mg/vial and 90 mg/vial	Aredia	
Pamidronate Disodium	Injection	30 mg/vial, 60 mg/vial and 90 mg/vial	Aredia	
Pantoprazole Sodium	For Injection	40 mg/vial	Prontonix IV	4/7/2005

Pantoprazole Sodium	Delayed-release Tablets	20 mg and 40 mg	Protonix	2/2/2004
Paroxetine Hydrochloride	Capsules	10 mg and 20 mg	Paxil	
Paroxetine Hydrochloride	Oral Suspension	10 mg/5 mL	Paxil	2/10/2005
Paroxetine Hydrochloride	Tablets	10 mg, 20 mg, 30 mg and 40 mg	Paxil	
Paroxetine Hydrochloride	Extended-release Tablets	25 mg	Paxil CR	9/9/2005
Pergolide Mesylate	Tablets	0.05 mg, 0.25 mg and 1 mg	Permax	
Pioglitazone Hydrochloride	Tablets	15 mg, 30 mg and 45 mg	Actos	
Polyethylene Glycol 3350	Powder for Oral Solution	17g/Scoopful	Miralax	
Potassium Chloride	Extended-release Capsules	8 mEq and 10 mEq	Micro K	
Potassium Chloride	Extended-release Tablets	10 mEq and 20 mEq	K-Dur	
Pramipexole Dihydrochloride	Tablets	0.25 mg	Mirapex	5/27/2005
Pramipexole Dihydrochloride	Tablets	0.125 mg, 0.5 mg, 1 mg and 1.5 mg	Mirapex	6/24/2005
Pravastatin Sodium	Tablets	10 mg, 20 mg, 40 mg and 80 mg	Pravachol	
Pravastatin Sodium	Tablets	30 mg	Pravachol	6/1/2005
Prazosin Hydrochloride	Capsules	1 mg, 2 mg and 5 mg	Minipress	
Prednisolone Sodium Phosphate	Oral Solution	5 mg(base)/ 5 mL and 15 mg (base)/ 5 mL	Pediapred	
Propofol	Injection	10 mg/mL ; 20 mL, 50 mL and 100 mL vials and 20 mL syringe	Diprivan	
Propranolol Hydrochloride	Extended-	60 mg, 80 mg,	Inderal LA	

	release Capsules	120 mg and 160 mg		
Quetiapine Fumarate	Tablets	25 mg	Seroquel	8/12/2005
Quetiapine Fumarate	Tablets	100 mg, 200 mg and 300 mg	Seroquel	2/21/2006
Quinapril Hydrochloride	Tablets	5 mg, 10 mg, 20 mg and 40 mg	Accupril	
Quinapril Hydrochloride/ Hydrochlorothiazide	Tablets	10 mg/12.5 mg, 20 mg/12.5 mg and 20mg/25 mg	Accuretic	
Rabeprazole Sodium	Delayed-release Tablets	20 mg	Aciphex	
Raloxifene Hydrochloride	Tablets	60 mg	Evista	
Ramipril	Capsules	1.25 mg, 2.5 mg, 5 mg and 10 mg	Altace	
Ranitidine	Capsules	150 mg and 300 mg	Zantac	
Ranitidine	Injection	25 mg/mL, 2 mL and 6 mL and 40 mL vials	Zantac	
Ranitidine	Oral Solution	15 mg/mL	Zantac	
Ranitidine	Tablets	75 mg, 150 mg and 300 mg	Zantac	
Repaglinide	Tablets	0.5 mg, 1 mg and 2 mg	Prandin	2/10/2005
Ribavirin	Capsules	200 mg	Rebetol	
Risedronate Sodium	Tablets	5 mg, 30 mg and 35 mg	Actonel	4/23/2004
Risperidone	Oral Solution	1 mg/mL	Risperdal	
Risperidone	Tablets	0.25 mg, 1 mg, 2 mg, 3 mg and 4 mg	Risperdal	
Risperidone	Orally Disintegrating Tablets	0.5 mg, 1 mg and 2 mg	Risperdal	

Risperidone	Orally Disintegrating Tablets	0.25 mg	Risperdal	6/27/2005
Rivastigmine Tartrate	Capsules	1.5 mg, 3 mg, 4.5 mg and 6 mg	Exelon	4/21/2004
Rivastigmine Tartrate	Oral Solution	2 mg/mL	Exelon	11/5/2004
Rizatriptan Benzoate	Tablets	5 mg and 10 mg	Maxalt	9/2/2004
Rizatriptan Benzoate	Orally Disintegrating Tablets	5 mg and 10 mg	Maxalt-MLT	2/17/2006
Rofecoxib	Tablets	12.5 mg, 25 mg and 50 mg	Vioxx	
Ropinirole Hydrochloride	Tablets	0.25 mg, 0.5 mg, 1 mg and 2 mg	Requip	12/22/2004
Ropinirole Hydrochloride	Tablets	3 mg, 4 mg and 5 mg	Requip	2/4/5005
Rosiglitazone Maleate	Tablets	2 mg, 4 mg and 8 mg	Avandia	
Rosiglitazone Maleate and Metformin Hydrochloride	Tablets	1 mg/ 500 mg, 2 mg/ 500mg, 4 mg/ 500 mg, 2 mg/ 1000 mg and 4 mg/ 1000 mg	Avandamet	10/22/2004
Sertraline Hydrochloride	Oral Concentrate	20 mg/mL	Zoloft	
Sertraline Hydrochloride	Tablets	25 mg, 50 mg and 100 mg	Zoloft	
Sertraline Hydrochloride	Tablets	150 mg and 200 mg	Zoloft	11/9/2005
Sevoflurane	Inhalation	100%, 250 mL	Ultane	
Sildenafil Citrate	Tablets	25 mg and 50 mg	Viagra	11/19/2004
Sildenafil Citrate	Tablets	100 mg	Viagra	10/25/2004
Silver Sulfadiazine	Cream	1%	Silvadene	
Simvastatin	Tablets	5 mg, 10 mg, 20 mg, 40 mg and 80 mg	Zocor	

Sumatriptan Succinate	Injection	6 mg/0.5 mL, 0.5 mL vials	Imitrex	10/25/2004
Sumatriptan Succinate	Tablets	25 mg, 50 mg and 100 mg	Imitrex	
Tamoxifen Citrate	Tablets	10 mg and 20 mg	Nolvadex	
Tamsulosin Hydrochloride	Capsules	0.4 mg	Flomax	12/20/2004
Terazosin Hydrochloride	Capsules	1 mg, 2 mg, 5 mg and 10 mg	Hytrin	
Terazosin Hydrochloride	Tablets	1 mg, 2 mg, 5 mg and 10 mg	Hytrin	
Terbinafine Hydrochloride	Tablets	250 mg	Lamisil	
Terfenadine	Tablets	60 mg	Seldane	
Testosterone	Gel	1%	Androgel	
Tiagabine Hydrochloride	Tablets	2 mg and 4 mg	Gabitril	2/1/2005
Ticlopidine Hydrochloride	Tablets	250 mg	Ticlid	
Timolol Maleate	Ophthalmic Solution	0.25% and 0.5%	Timoptic	
Tolterodine Tartrate	Tablets	1 mg and 2 mg	Detrol	
Topiramate	Capsules	15 mg and 25 mg	Topamax Sprinkle	9/7/2005
Topiramate	Tablets	25 mg, 100 mg and 200 mg	Topamax	12/26/2001
Topiramate	Tablets	50 mg	Topamax	9/8/2005
Torsemide	Tablets	5 mg, 10 mg, 20 mg, and 100 mg	Demadex	
Tramadol Hydrochloride	Tablets	50 mg	Ultram	
Trandolapril	Tablets	1 mg, 2 mg and 4 mg	Mavik	10/4/2004
Trazodone Hydrochloride	Tablets	150 mg	Desyrel	
Tretinoin	Cream	0.025%, 0.05% and 0.1%	Retin-A	
Tretinoin	Gel	0.025%	Retin-A	
Triamcinolone Acetonide	Nasal Spray	0.055 mg/Spray	Nasacort AQ	12/29/2005
Triamterene/ Hydrochlorothiazide	Tablets	37.5 mg/25 mg	Maxzide	

		and 75 mg/50 mg		
Valganciclovir Hydrochloride	Tablets	450 mg	Valcyte	12/27/2005
Valsartan	Tablets	40 mg, 80 mg, 160 mg and 320 mg	Diovan	12/28/2004
Valacyclovir Hydrochloride	Tablets	500 mg and 1 g	Valtrex	
Valsartan and Hydrochlorothiazide	Tablets	80 mg/12.5 mg, 160 mg/12.5 mg and 160 mg/25 mg	Diovan HCT	12/2/2005
Venlafaxine Hydrochloride	Extended-release Capsules	37.5 mg, 75 mg and 150 mg	Effexor XR	
Venlafaxine Hydrochloride	Tablets	25 mg, 37.5 mg, 50 mg, 75 mg and 100 mg	Effexor	11/03/2005
Vecuronium Bromide	For Injection	10 mg/vial and 20 mg/vial	Norcuron	
Verapamil Hydrochloride	Extended-release Capsules	120 mg, 180 mg and 240 mg	Verelan SR	
Verapamil Hydrochloride	Extended-release Tablets	180 mg	Isoptin SR	
Verapamil Hydrochloride	Extended-release Tablets	240 mg	Covera HS	
Vincristine Sulfate	Injection	1 mg/mL, 1 mL, 2 mL and 5 mL vials	Oncovin	
Zaleplon	Capsules	5 mg and 10 mg	Sonata	6/21/2005
Zidovudine	Capsules	100 mg	Retrovir	
Ziprasidone Hydrochloride	Capsules	20 mg, 40 mg, 60 mg and 80 mg	Geodon	2/7/2005
Zolpidem Tartrate	Extended-release Tablets	6.25 mg>	Ambien CR	2/24/2006
Zolpidem Tartrate	Extended-	12.5 mg	Ambien CR	1/19/2006

	release Tablets		
--	-----------------	--	--

[↑ Back to Top](#) [↖ Back to OGD](#)

Date created: February 16, 2005; Updated June 22, 2006

[CDER Home Page](#) | [CDER Site Info](#) | [Contact CDER](#) | [What's New @ CDER](#)
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#) | [HHS Home Page](#)

FDA/Center for Drug Evaluation and Research

EXHIBIT D

CONFIDENTIAL – FILED UNDER SEAL

EXHIBIT E

FINAL

WYETH
WORLDWIDE NET REVENUE BY PRODUCT
THREE MONTHS ENDED MARCH 31, 2006
(000's)
(UNAUDITED)

	DOMESTIC				INTERNATIONAL				TOTAL			
	1ST QTR 2006	1ST QTR 2005	DOLLAR CHANGE	PERCENT CHANGE	1ST QTR 2006	1ST QTR 2005	DOLLAR CHANGE	PERCENT CHANGE	1ST QTR 2006	1ST QTR 2005	DOLLAR CHANGE	PERCENT CHANGE
<i>Wyeth Pharmaceuticals</i>												
EFEXOR	\$ 622,112	\$ 576,131	\$ 45,981	8.0%	\$ 322,537	\$ 292,568	\$ 30,169	10.3%	\$ 944,649	\$ 868,499	\$ 76,150	8.8%
PROTONIX	481,572	409,444	72,128	17.6%	-	-	-	N/A	481,572	409,444	72,128	17.6%
PREVNAR	258,771	260,057	(1,286)	-0.5%	172,787	130,999	41,788	31.9%	431,558	391,036	40,502	10.4%
ENBREL	-	-	-	N/A	335,355	236,971	98,384	41.5%	335,355	236,971	98,384	41.5%
NUTRITIONALS	1,360	4,240	(2,880)	-67.9%	287,173	250,246	36,927	14.8%	288,533	254,486	34,047	13.4%
PREMARIN FAMILY	241,166	174,829	66,337	37.9%	24,403	36,084	(11,681)	-32.4%	265,569	210,913	54,656	25.9%
ZOSYN/AZOCIN	127,378	115,994	11,384	9.8%	111,042	113,261	(2,219)	-2.0%	238,420	229,255	9,165	4.0%
CONTRACEPTIVES	21,203	23,699	(2,496)	-10.5%	105,879	116,323	(10,444)	-9.0%	127,082	140,022	(12,940)	-9.2%
BENEFIX	76,619	77,198	(579)	-0.8%	13,033	11,703	1,330	11.4%	89,652	88,901	751	0.8%
RAPAMUNE	44,410	42,554	1,856	4.4%	31,364	29,579	1,785	6.0%	75,774	72,133	3,641	5.0%
REFACTO	13,975	11,259	2,716	24.1%	53,319	52,289	1,030	2.0%	67,294	63,548	3,746	5.9%
BMP-2	64,488	51,249	13,239	25.8%	792	343	449	130.9%	65,280	51,592	13,688	26.5%
ZOTON	-	-	-	N/A	40,505	124,073	(83,568)	-67.4%	40,505	124,073	(83,568)	-67.4%
TYGACIL	9,644	-	9,644	N/A	510	-	510	N/A	10,154	-	10,154	N/A
subtotal	1,962,698	1,746,634	216,044	12.4%	1,498,699	1,394,239	104,460	7.3%	3,461,397	3,140,893	320,504	10.2%
OTHER PHARMACEUTICALS	73,567	96,604	(23,037)	-23.8%	246,445	283,996	(37,551)	-13.2%	320,012	380,600	(60,588)	-15.9%
ALLIANCE REVENUE	219,742	167,344	52,398	31.3%	34,361	28,632	5,729	20.0%	254,103	195,976	58,127	29.7%
TOTAL WYETH PHARMACEUTICALS	\$ 2,256,007	\$ 2,010,602	\$ 245,405	12.2%	\$ 1,779,505	\$ 1,706,867	\$ 72,638	4.3%	\$ 4,035,512	\$ 3,717,469	\$ 318,043	8.6%
FORT DODGE	116,145	117,321	(1,176)	-1.0%	132,094	127,418	4,676	3.7%	248,239	244,739	3,500	1.4%
TOTAL PHARMACEUTICALS	\$ 2,372,152	\$ 2,127,923	\$ 244,229	11.5%	\$ 1,911,599	\$ 1,834,285	\$ 77,314	4.2%	\$ 4,283,751	\$ 3,962,208	\$ 321,543	8.1%
<i>Wyeth Consumer Healthcare</i>												
CENTRUM	\$ 81,854	\$ 66,416	\$ 15,438	23.2%	\$ 75,768	\$ 74,422	\$ 1,346	1.8%	\$ 157,622	\$ 140,838	\$ 16,784	11.9%
ADVIL	102,099	94,133	7,966	8.5%	40,436	34,005	6,431	18.9%	142,555	128,138	14,397	11.2%
CALTRATE	14,891	16,307	(1,416)	-8.7%	31,832	28,680	3,152	11.0%	46,723	44,987	1,736	3.9%
ROBITUSSIN	22,207	49,109	(26,902)	-54.6%	10,480	11,424	(944)	-8.3%	32,787	60,533	(27,746)	-45.8%
PREPARATION H	18,852	19,903	(1,051)	-5.3%	4,660	6,136	(1,476)	-24.1%	23,512	26,039	(2,527)	-9.7%
CHAPTICK	18,487	22,141	(3,654)	-16.5%	3,320	4,463	(1,143)	-25.6%	21,807	26,604	(4,797)	-18.0%
ADVIL COLD & SINUS	2,031	18,541	(16,510)	-89.0%	8,609	8,955	(346)	-3.9%	10,640	27,496	(16,856)	-61.3%
OTHER	34,877	65,759	(30,882)	-47.0%	83,683	96,396	(12,713)	-13.2%	118,560	162,155	(43,595)	-26.9%
TOTAL CONSUMER HEALTHCARE	\$ 295,398	\$ 352,309	\$ (56,911)	(16.2)%	\$ 258,788	\$ 264,481	\$ (5,693)	(2.2)%	\$ 554,186	\$ 616,790	\$ (62,604)	(10.1)%
<i>Wyeth</i>												
TOTAL PHARMACEUTICALS	\$ 2,372,152	\$ 2,127,923	\$ 244,229	11.5%	\$ 1,911,599	\$ 1,834,285	\$ 77,314	4.2%	\$ 4,283,751	\$ 3,962,208	\$ 321,543	8.1%
TOTAL CONSUMER HEALTHCARE	295,398	352,309	(56,911)	-16.2%	258,788	264,481	(5,693)	(2.2)%	554,186	616,790	(62,604)	-10.1%
TOTAL WYETH	\$ 2,667,550	\$ 2,480,232	\$ 187,318	7.6%	\$ 2,170,387	\$ 2,098,766	\$ 71,621	3.4%	\$ 4,837,937	\$ 4,578,998	\$ 258,939	5.7%

Note: Certain reclassification adjustments have been made in 2005 in order to conform to the 2006 presentation.

FINAL

WYETH PHARMACEUTICALS
PREMARIN FAMILY
NET REVENUE
(UNAUDITED)

THREE MONTHS ENDED MARCH 31, 2006

	2006	2005	\$ Chg	% Chg	2006 % of Total
<u>Domestic:</u>					
Premarin	\$ 191,758	\$ 119,967	\$ 71,791	59.8%	79.5%
Prempro/phase	49,408	54,862	(5,454)	-9.9%	20.5%
Premarin Family	241,166	174,829	66,337	37.9%	100.0%
<u>International:</u>					
Premarin	16,789	22,230	(5,441)	-24.5%	68.8%
Prempro/phase	7,614	13,854	(6,240)	-45.0%	31.2%
Premarin Family	24,403	36,084	(11,681)	-32.4%	100.0%
<u>Total:</u>					
Premarin	208,547	142,197	66,350	46.7%	78.5%
Prempro/phase	57,022	68,716	(11,694)	-17.0%	21.5%
Premarin Family	\$ 265,569	\$ 210,913	\$ 54,656	25.9%	100.0%

EXHIBIT F

PROSKAUER ROSE LLP
Judson L. Hand (JH-1189)
One Newark Center, 18th Floor
Newark, NJ 07102
973-274-3200

Attorneys for Defendants
Sun Pharmaceutical Industries Ltd. and
Sun Pharmaceutical Advanced Research Centre

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ALTANA PHARMA AG and WYETH,

Plaintiffs,

v.

SUN PHARMACEUTICAL INDUSTRIES
LTD. and SUN PHARMACEUTICAL
ADVANCED RESEARCH CENTRE

Defendants.

Civil Action No.: 05-1966 (JLL)

**SUN PHARMACEUTICAL INDUSTRIES LTD. AND SUN
PHARMACEUTICAL ADVANCED RESEARCH CENTRE'S
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendants Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Advanced
Research Centre (hereinafter collectively "Sun"), by their attorneys, for their Answer respond as
follows:

THE PARTIES

1. Sun is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 1 of the Complaint and therefore denies them.
2. Sun is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 2 of the Complaint and therefore, denies them.
3. Paragraph 3 is not a factual or legal allegation and requires no response.
4. Admitted.
5. Sun denies the allegations of ¶ 5 of the Complaint except admits that Sun Pharmaceutical Research Centre (the correct name for the entity) is a division of Sun Pharmaceutical Industries, Ltd., and is located at NIMA Compound, Near Pratham Enclave, Tandalja Road, Baroda 390020, India.
6. Admitted.
7. Paragraph 7 is not a factual or legal allegation and requires no response.
8. Admitted.
9. Sun admits that it markets pharmaceutical products in the United States, including in New Jersey. Sun denies ¶ 9 of the Complaint in all other respects.
10. Sun admits that it manufactures pharmaceutical products and bulk pharmaceuticals that are sold and used in the United States, including in New Jersey. Sun denies ¶ 10 of the Complaint in all other respects.
11. Sun admits that it has authorized Mr. Guttman to accept service of process on behalf of Sun and has consented to personal jurisdiction and venue in New Jersey. Sun denies ¶ 11 of the Complaint in all other respects.

12. Upon information and belief, Sun admits that New Drug Application No. 20-987 was approved by the United States Food & Drug Administration for 20 mg and 40 mg delayed-release tablets including the active ingredient pantoprazole sodium, and such tablets are prescribed for gastro-intestinal disorders associated with acid secretion. Upon information and belief, Sun admits that such tablets are promoted in the United States under the trade name "PROTONIX®." To the extent not admitted, Sun is without further information sufficient for a belief as to the truth or falsity of the remaining allegations found in ¶ 12 of the Complaint and, therefore denies them.

13. Sun admits that United States Patent No. 4,758,579 ("the '579 patent") issued on July 19, 1988, and that it purports to disclose certain compounds allegedly useful for inhibiting gastric acid secretion. Sun is without information sufficient to form a belief as to the truth or falsity of the remaining allegations found in ¶ 13 of the Complaint and therefore denies them.

14. Sun is without sufficient information to form a belief as to the truth or falsity of the allegations found in ¶ 14 of the Complaint and, therefore, denies them.

15. Sun admits that a copy of the '579 patent was attached as Exhibit A to the Complaint.

16. Admitted.

17. Admitted.

18. Admitted.

19. Sun is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 19 of the Complaint and therefore denies them.

20. Sun is without information sufficient to form a belief as to the truth or falsity of the allegations in ¶ 20 of the Complaint and therefore denies them.

21. Sun denies that it infringes any valid and enforceable claim of the '579 patent.

22. Denied.

23. Denied, except that Sun admits it was aware of the existence of the '579 patent.

24. Denied.

25. Denied.

26. Denied.

PRAYER FOR RELIEF

27. In response to Plaintiffs' prayer for relief in the Complaint:

a. Sun denies that Plaintiffs are entitled to the relief requested in ¶ 27(a) of the Prayer for Relief.

b. Sun denies that Plaintiffs are entitled to the relief requested in ¶ 27(b) of the Prayer for Relief.

c. Sun denies that Plaintiffs are entitled to the relief requested in ¶ 27(c) of the Prayer for Relief.

d. Sun denies that Plaintiffs are entitled to the relief requested in ¶ 27(d) of the Prayer for Relief.

e. Sun denies that Plaintiffs are entitled to the relief requested in 27(e) of the Prayer for Relief.

f. Sun denies that Plaintiffs are entitled to the relief requested in ¶ 27(f) of the Prayer for Relief.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

28. Upon information and belief, the claims of the '579 patent are invalid, void and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 132, 135, 256 and 287.

SECOND AFFIRMATIVE DEFENSE

29. Sun will not infringe any valid and enforceable claim of the '579 patent under 35 U.S.C. § 271.

THIRD AFFIRMATIVE DEFENSE

30. The claims of the '579 patent which purport to cover pantoprazole are invalid under the judicially created doctrine of obviousness type double patenting.

FOURTH AFFIRMATIVE DEFENSE

31. Plaintiffs fail to state a valid claim for willful infringement.

COUNTERCLAIMS

Sun, for its counterclaims against Plaintiffs, alleges as follows:

THE PARTIES

1. Sun Pharmaceutical Industries Ltd. is a public limited liability company incorporated and existing under the laws of the State of India, and has a principal place of business located at Acme Plaza, Andheri Kurla Road, Andheri (East), Mumbai 400059, Maharashtra, India.

2. Upon information and belief, Altana is a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany.

3. Upon information and belief, Wyeth is a Delaware corporation with its headquarters located at Five Giralda Farms, Madison, New Jersey 07940.

JURISDICTION

4. This is a declaratory judgment action under 28 U.S.C. §§ 2201 and 2202. The counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* and under the Food, Drug and Cosmetic Act of the United States, 21 U.S.C. § 355(j). Jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 21 U.S.C. § 355(j).

5. Altana Pharma AG (hereinafter "Altana") and Wyeth have filed a patent infringement lawsuit against Sun.

FACTUAL BACKGROUND

6. Upon information and belief, Altana is currently the owner of the United States Letters Patent Nos. 4,758,579 (the '579 patent).

7. Upon information and belief, Wyeth Pharmaceuticals, Inc., a wholly-owned subsidiary of Wyeth, holds an improved New Drug Application from the FDA for pantoprazole sodium delayed-release tablets.

8. Sun has filed ANDA No. 77-058 for approval to market a pantoprazole sodium delayed-release tablet, eq. 20 mg and 40 mg base in the United States.

9. Sun sent a notice letter related to ANDA No. 77-058 pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to Wyeth and Altana on March 1, 2005, which notice letters, upon

information and belief, were received by Altana on or about March 8, 2005, and by Wyeth on or about March 4, 2005, respectively. Sun also sent earlier notice letters to both Altana and Wyeth.

10. On or about April 13, 2005, Altana and Wyeth filed or caused to be filed a Complaint for patent infringement which alleges that Sun infringes the '579 patent.

COUNT I

INVALIDITY OF THE '579 PATENT

11. The allegations of ¶¶ 1-10 of Sun's Counterclaims are repeated, realleged, and incorporated herein by reference.

12. Upon information and belief, the claims of the '579 patent are invalid, void and/or unenforceable for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 132, 135, 256 and 287.

13. The claims of the '579 patent are invalid under the judicially created doctrine of obviousness type double patenting.

COUNT II

NON-INFRINGEMENT OF THE '579 PATENT

14. The allegations of ¶¶ 1-13 of Sun's Counterclaims are repeated, realleged and incorporated herein by reference.

15. Sun will not infringe any valid and enforceable claim of the '579 patent under 35 U.S.C. § 271.

PRAYER FOR RELIEF

WHEREFORE, Sun prays that the Court enter:

A. A declaratory judgment that the '579 patent is invalid;

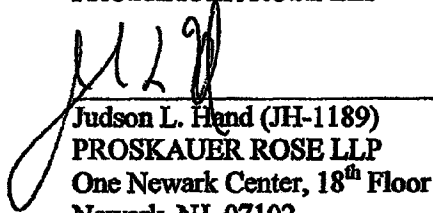
B. A declaratory judgment that Sun will not infringe any valid and enforceable claim of the '579 patent under 35 U.S.C. § 271;

C. An Order enjoining and restraining Altana and Wyeth and their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them from further charges of infringement or acts of enforcement based on the '579 patent against Sun, its actual and prospective customers, suppliers, clinical investigators, and anyone in privity with Sun; and

D. An Order awarding Sun such other further relief as the Court deems just and equitable.

Dated: May 5, 2005

PROSKAUER ROSE LLP



Judson L. Hand (JH-1189)
PROSKAUER ROSE LLP
One Newark Center, 18th Floor
Newark, NJ 07102
973-274-3200

Charles Guttman
James H. Shalek
PROSKAUER ROSE LLP
1585 Broadway
New York, New York 10036
(212) 969-3000

Attorneys for Defendants
Sun Pharmaceutical Industries Ltd. and
Sun Pharmaceutical Advanced Research Centre